Washington University in St. Louis
SCHOOL OF MEDICINE

Division of Radiological Sciences

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fischers Lane, room 1061
Rockville, MD 20852

July 13, 2005

Docket No. 2005D-0122

Comments on:
Draft Guidance for Industry, Investigators, and Reviewers
Exploratory IND Studies

Dear Commissioner:

I want to say that I am pleased the FDA is moving in the direction of making the IND process less cumbersome, and hopefully this will expedite the overall timeline for submission and review.

I do have several question/comments relating to Page 9 of the Draft Guidance, lines 317-332. I would like the Extended Single-Dose Toxicity Studies clarified, and moved to a separate section which is presented prior to the clinical studies of pharmacokinetics or imaging. Within that section I would like clarification of what is meant in line 319 of... justified by in vitro metabolism data and by comparative data on in vitro pharmacodynamic effects. Possibly you could prepare a one-page information sheet similar to the August 1996 Guidance for Single Dose Acute Toxicity Testing for the draft Extended Single-Dose Toxicity Testing, or use the EMEA format of the "Position Paper on Non-Clinical Safety Studies to Support Clinical Trials with a Single Microdose" referenced in the FDA draft Guidance. This would help outline the steps required in the toxicity testing.

Thank you for your time.

Sincerely,

Sally Schwarz

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